

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/
FENFLURAMINE/DEXFENFLURAMINE)) MDL NO. 1203
PRODUCTS LIABILITY LITIGATION)

THIS DOCUMENT RELATES TO:)

SHEILA BROWN, et al.) CIVIL ACTION NO. 99-20593
v.)

AMERICAN HOME PRODUCTS) 2:16 MD 1203
CORPORATION)

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8885

Bartle, J.

June 6, 2012

Anita L. Myers ("Ms. Myers" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust").² Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").³

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Joseph B. Myers, claimant's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their

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To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In October, 2004, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Randall G. Johnson, M.D. Based on an echocardiogram dated July 17, 2002, Dr. Johnson attested in Part II of claimant's Green Form that Ms. Myers suffered from moderate mitral regurgitation, an abnormal left atrial dimension, and a reduced ejection fraction

3. (...continued)

medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1) - (2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

in the range of 50% to 60%.⁴ Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$496,153.⁵

In the report of claimant's echocardiogram, the reviewing cardiologist, Muhammad Yasin, M.D., stated that Ms. Myers had "[m]ild to moderate mitral" regurgitation. Dr. Yasin, however, did not specify a percentage as to claimant's level of mitral regurgitation. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA"), in any apical view, is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In September, 2005, the Trust forwarded the claim for review by Karen K. Hamilton, M.D., F.A.C.C., one of its auditing cardiologists. In audit, Dr. Hamilton concluded that there was no reasonable medical basis for Dr. Johnson's finding that claimant had moderate mitral regurgitation because claimant's

4. Dr. Johnson also attested that Ms. Myers suffered from New York Heart Association Functional Class I symptoms. This condition is not at issue in this claim.

5. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.C.(2)(b). As the Trust does not contest the attesting physician's finding of an abnormal left atrial dimension, which is one of the complicating factors needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

echocardiogram demonstrated only mild mitral regurgitation. In support of this conclusion, Dr. Hamilton stated that "[t]he [mitral regurgitant] jets in this patient were very very small and nowhere even close to 20% of [the left atrial] area. No jets were traced on the tape so I'm not sure where the attesting [physician] measured."

Based on the auditing cardiologist's finding of mild mitral regurgitation, the Trust issued a post-audit determination denying the claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.⁶ In contest, claimant argued that under the reasonable medical basis standard, the attesting physician's conclusions should be accepted unless they are "extreme or excessive." Claimant further contended that "[q]uantifying the level of regurgitation shown on an echocardiogram is inherently subjective."⁷ Claimant also submitted that the Trust did not properly apply the "reasonable medical basis" standard

6. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to the claim of Ms. Myers.

7. In support of this argument, claimant submitted excerpts of depositions of five physicians from other proceedings. None of the testimony submitted by Ms. Myers, however, specifically addressed claimant's echocardiogram.

established in the Settlement Agreement as the auditing cardiologist simply substituted her own opinion for that of the attesting physician.⁸ In addition, Ms. Myers argued that Dr. Johnson's conclusion of moderate mitral regurgitation was reasonable because it was consistent with the findings of Muhammad Yasin, M.D., the physician who interpreted the echocardiogram in the Trust's Screening Program. See Settlement Agreement § IV.A.1. Finally, claimant argued that because the auditing cardiologist did not dispute that Ms. Myers had an abnormal left atrial dimension, there is a reasonable medical basis for her claim because "[a]n enlarged left atrium is one of the possible complicating factors known to be caused by mitral regurgitation."⁹

The Trust then issued a final post-audit determination again denying the claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c).

8. Claimant also contended that the Trust should ensure that its auditing cardiologists do not have any "biases" against claimants. As there is no evidence of any "bias," this issue is irrelevant for resolution of this claim. Similarly, claimant referenced, without any substantive discussion, a pleading in MDL 1203. As claimant has not attempted to establish how this filing entitles her to Matrix Benefits, it is not pertinent to the disposition of this show cause claim.

9. Claimant did not provide any expert submission in support of this assertion.

The Trust then applied to the court for issuance of an Order to show cause why the claim should be paid. On May 2, 2007, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 7161 (May 2, 2007).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on August 16, 2007, and claimant submitted a surreply on September 5, 2007. The Show Cause Record is now before the court for final determination. See Audit Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding that she had moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Myers reasserts the arguments that she made in contest.¹⁰ Claimant also contends that it is not uncommon for two cardiologists to review the same echocardiogram and to find different levels of regurgitation and, as such, "[n]either diagnosis is correct or incorrect; both fall within the realm of having a 'reasonable medical basis.'" She states that the "district court has made three plain errors in its rulings, regarding the proper interpretation of echocardiograms under the Settlement Agreement which have effectively barred the auditing cardiologist from using 'normal clinical judgment' or 'accepted medical standards.'" Finally, claimant submits that the court's determinations that the level of mitral regurgitation can only be determined through the use of color flow Doppler and that a single measurement of the level of mitral regurgitation is not sufficient to recover Matrix Benefits are erroneous and have "made it impossible for the Claimant to have her echocardiogram audited under 'normal clinical judgment' and 'accepted medical standards.'"¹¹

10. In further support of the argument made during contest that the Trust did not properly apply the "reasonable medical basis" standard, claimant refers to Dr. Hamilton's conclusion in connection with another show cause claim. As the issue is whether Ms. Myers has established a reasonable medical basis for her claim, Dr. Hamilton's conclusion as to a different claimant is irrelevant.

11. In addition, claimant asserts that the Trust's reliance on PTO No. 5229 (May 18, 2005) is misplaced. As we do not base our (continued...)

In her surreply, claimant reiterates that the definition of "reasonable medical standard" requires the auditing cardiologist to consider "all the Doppler modalities in their findings." In addition, Ms. Myers asserts that the geographic proximity of the attesting physician's office to claimant's home is irrelevant to whether the echocardiogram was properly interpreted.¹²

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. First, claimant does not adequately contest Dr. Hamilton's finding of mild mitral regurgitation. Despite the opportunity in contest to present additional evidence in support of her claim, Ms. Myers rests only on Dr. Johnson's check-the-box diagnosis on her Green Form. She does not respond to Dr. Hamilton's specific determination that the mitral regurgitant jets were "very very small and nowhere even close to 20%." Claimant never identified any particular error in Dr. Hamilton's conclusions. Mere disagreement with the auditing cardiologist without identifying any specific errors by

11. (...continued)

decision on the reviewing cardiologist's use of the word "mild" in the echocardiogram report, we need not reach this argument.

12. Claimant also asserts that she should be allowed discovery as to whether the Trust provides instructions to auditing cardiologists regarding the use of continuous wave Doppler. We disagree. See Audit Rule 41. Further, the issue of continuous wave Doppler is irrelevant as claimant never asserts that the use of continuous wave Doppler reveals the requisite level of mitral regurgitation.

the auditing cardiologist is insufficient to meet a claimant's burden of proof. On this basis alone, claimant has failed to meet her burden of demonstrating that there is a reasonable medical basis for her claim.

We also disagree with claimant's characterization of the reasonable medical basis standard. We are required to apply the standards delineated in the Settlement Agreement and the Audit Rules. The context of these two documents leads us to interpret the "reasonable medical basis" standard as more stringent than claimant contends, and one that must be applied on a case-by-case basis.¹³ Here, Dr. Hamilton determined in audit, and Ms. Myers does not adequately dispute, that the attesting physician's finding of moderate mitral regurgitation was unreasonable. Contrary to claimant's argument, Dr. Hamilton properly applied the reasonable medical basis standard established under the Settlement Agreement.¹⁴

Moreover, as we previously explained in PTO No. 2640, conduct "beyond the bounds of medical reason" can include:

13. For this reason as well, we reject claimant's assertion that an attesting physician's finding should always be accepted unless it constitutes medical malpractice.

14. We find that this is not merely conflicting "subjective" diagnoses between the attesting physician and the auditing cardiologist. Nor has Dr. Hamilton merely substituted her opinion for that of the attesting physician. Instead, Dr. Hamilton specifically determined claimant's echocardiogram did not support the attesting physician's finding of moderate mitral regurgitation.

(1) failing to review multiple loops and still frames; (2) failing to have a Board Certified Cardiologist properly supervise and interpret the echocardiogram; (3) failing to examine the regurgitant jet throughout a portion of systole; (4) over-manipulating echocardiogram settings; (5) setting a low Nyquist limit; (6) characterizing "artifacts," "phantom jets," "backflow" and other low velocity flow as mitral regurgitation; (7) failing to take a claimant's medical history; and (8) overtracing the amount of a claimant's regurgitation. See PTO No. 2640 at 9-13, 15, 21-22, 26. Here, Dr. Hamilton determined in audit, and Ms. Myers does not adequately dispute, that the attesting physician's finding of moderate mitral regurgitation was based on incorrectly characterizing "very very small" regurgitant jets "nowhere even close to 20% of [the left atrial] area" as moderate mitral regurgitation. Such an unacceptable practice cannot provide a reasonable medical basis for the resulting diagnosis and Green Form representation of moderate mitral regurgitation.

Finally, we reject claimant's assertion that she is entitled to Matrix Benefits because the echocardiogram that forms the basis of the claim for Matrix Benefits was conducted in the Screening Program for Fund A Benefits under the Settlement Agreement. See Settlement Agreement § IV.A. The Settlement Agreement clearly provides that the sole benefit that a class

member is entitled to receive based on an echocardiogram performed in the Screening Program is a limited amount of medical services or a limited cash payment:

All Diet Drug Recipients in Subclass 2(b) and those Diet Drug Recipients in Subclass 1(b) who have been diagnosed by a Qualified Physician as FDA Positive by an Echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period, will be entitled to receive, at the Class Member's election, either (i) valve-related medical services up to \$10,000 in value to be provided by the Trust; or (ii) \$6,000 in cash.

Id. § IV.A.1.c. Thus, by the plain terms of the Settlement Agreement, a Screening Program echocardiogram does not automatically entitle a claimant to Matrix Benefits.

Indeed, this conclusion is confirmed by the Settlement Agreement provisions concerning claimants eligible for Matrix Benefits. Specifically, claimants receiving a diagnosis of FDA Positive or mild mitral regurgitation merely become eligible to seek Matrix Benefits. See id. § IV.B.1. Further, adopting claimant's position would be inconsistent with Section VI.E. of the Settlement Agreement, which governs the audit of claims for Matrix Benefits, as well as this court's decision in PTO No. 2662 (Nov. 26, 2002), which mandated a 100% audit requirement for all claims for Matrix Benefits. As nothing in the Settlement Agreement supports the conclusion that a favorable Screening Program echocardiogram for purposes of Fund A Benefits results in

an immediate entitlement to Matrix Benefits, we decline claimant's request to interpret the Settlement Agreement in this fashion.

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of both the claim of Ms. Myers for Matrix Benefits and the related derivative claim submitted by her spouse.